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EDITORIAL COMMENT

The Impact of IMPACT

A Game Changer for Congenital Cardiology*

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"I was so much older then,
I'm younger than that now"
—Bob Dylan (1)

Across the years, standardization of care for children and adults with congenital heart disease has paled in comparison with that witnessed for acquired heart disease. Congenital cardiology's experience with multicenter outcomes trials, national registries, development and assessment of provider-centered and patient-centered quality indicators, care guidelines, and certification of specialty training have either been limited in scope or in foundation data, are newly developing, or have yet to be embarked upon. For multiple reasons, including the perception of an imperative to act and intervene in the face of impending poor outcomes at young ages, early decades of growth and development of the congenital cardiology field appeared to perpetuate a mindset of "invention turned into intervention" across the lifelong spectrum of pathology. This culture allowed novel technological advances and both paralleled and likely contributed to documented improvements in both acute and longer term survival for some of medicine's most at-risk populations.

"For the times they are a-changin'"
—Bob Dylan (2)

The difference between "invention" and "innovation" can be blurred in the process of discovery, as the demonstration of value and worth attendant with particular novelty requires structured acute and longitudinal assessment and analysis. As congenital cardiologists felt increasingly established (and empowered to self-reflect) and as stark risks of mortality shifted away from early and later pediatric years through a more chronic phase in young and older adulthood, the need to assess and analyze the lifelong implications (via structure and rigor in acute and longitudinal outcomes assessment over the age spectrum) of congenital interventions was increasingly recognized and accepted. Now, through the vision of National Cardiovascular Data Registry's (NCDR's) IMPACT (Improving Pediatric and Congenital Treatment) Registry, this awareness is placed into widespread application.

"I came in from the wilderness,
a creature void of form"
—Bob Dylan (3)

Numerous efforts to catalogue and register congenital interventions preceded IMPACT. The Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) Registry, an unfunded collection of data from 27 congenital catheterization centers, began in 1982 and called for voluntary reporting of limited and basic data elements (4). VACA investigators' demonstration of factors associated with increased procedural risks for most common congenital interventions promulgated a sense of collaborative purpose that continued through the mid-1990s. In the mid-2000s, small groups of partnering practices and institutions (MAGIC [Mid-Atlantic Group of Interventional Cardiology] and the CCISC [Congenital Cardiovascular Interventional Study Consortium]), trialed limited structured systems for capturing specific procedural and outcomes data elements. The ongoing multicenter collaborative Congenital Cardiac Catheterization Project on Outcomes (C3PO), funded by participating institutions, created a data collection model of sufficient scope to allow development of risk

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adjustment scales and more rigorous description and assessment of procedural technique and adversity across the patient age spectrum seen in pediatric cardiology practices (5). C3PO increased recognition of the need for definition of procedural goals, technique success and adversity; standardization of indication, procedure follow, and assessment; and data capture, core review, attribution, and systematic analysis. Combined, these registries demonstrated areas of glitch, as well as the need for future feedback systems that would allow development of improved and meaningful risk stratification schema, assessment of attribution and outcomes (on the basis of currently accepted indications and procedure), and determination of value and worth. With such accomplishment, indication and procedural technique refinements could occur, with subsequent improvement in care for persons affected by congenital heart disease.

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"Let us not talk falsely now,
the hour is getting late"

– Bob Dylan (6)

In this issue of the *Journal*, Moore et al. (7), who comprise members of the steering committee of IMPACT, report on findings from the initial efforts of this registry. The finding may underwhelm the casual reader, but on further reflection, the serious reader will be impressed by the humility demonstrated in the pursuit of accuracy. Beginnings of procedural definitions emerged, and patient and procedural characteristics are catalogued; significant limitations in these are recognized, allowing the registry the ability to learn, reflect, and refine. The authors avoid terms such as *success* related to procedure or outcomes, recognizing that the true 2-fold triumph of these initial efforts: bringing together a congenital community that overwhelmingly endorsed participation in this registry and avoiding overstatement or overinterpretation of results. In so doing, Moore et al., representing IMPACT Registry participants, confirm that the congenital cardiology field has matured and come of age and can now can tackle some of its most difficult questions relating to outcomes, quality, and worth.

"How many deaths will it take till [we know]
that too many people have died?"

–Bob Dylan (8)

The NCDR has long demonstrated that with registries comes standard and improved abilities to assess outcomes meaningful to patient care practice, science, and health care resource allocation. Much credit is due to the American College of Cardiology and its Adult Congenital/Pediatric Cardiology Council, as well as to the overarching NCDR and IMPACT Registry leadership for their creation and rapid-phase beginning via collection of important procedural data from congenital cardiology centers. The efforts of Moore et al. (7) in this issue of the *Journal*, representing the steering committee and the many IMPACT participants, deserve praise. However, from these humble beginnings, great expectations remain. The stage has been clearly set for the future of congenital cardiology. Where must IMPACT and congenital cardiology go from here?

- The IMPACT Registry has the potential to drive practice toward the mean of measured performance. Until outcomes, worth, and value are determined for particular aspects of interventions, care must be taken to set the highest expectations for procedural accomplishment, as well as for both completeness and accuracy of documentation.
- Structure and rigor must be sustained at all levels of review, analysis, and reflection. The current effort by Moore et al. (7) must lead to far more sophisticated and aggressively critical analyses of specific aspects of specific interventions. The field must call itself to task as limitations and biases must be recognized and reflected on and steps taken to improve definition, data collection, and performance. Analysis must lead to change in care recommendation and, ultimately, in practice.
- IMPACT collects data largely from pediatric congenital heart disease centers. It has long been recognized that a large (if not major) percent of surgical and catheter-based interventions in adults with congenital heart disease (and general medical care for such adults), who now comprise more than one-half of the congenital heart disease population, are performed by physicians not identified as congenital heart disease specialists and not necessarily in conjunction with congenital heart disease specialty care teams (9). The morbid and mortal consequences of such practices were questioned, placing global cooperation of the pediatric, internal medicine, and congenital cardiology communities into tension (10). Only with incorporation of all internal medicine cardiology practices (such as those already in other adult NCDRs) into IMPACT will the totality of real-world practice of interventions for young and older adults with congenital heart disease be recognized. When this occurs, the performance, outcomes, quality, and worth of concentrating care within a subspecialty can be appropriately examined, and our larger

cardiovascular care communities will be able to work most appropriately together toward common goals.

- Structural intervention is a small part of the whole of "innovation" and improved outcomes. Congenital cardiology has seen a shift in mortality, for some from neonatal to so-called interstage periods (the years or decades between interventions) and for most others, pushed into premature adulthood. The modern natural history of congenital heart disease in its variety, as well as the longer term physiological consequences of medical interventions and aging, remains largely unknown or uncertain. An organized national longitudinal registry of medical (in addition to structural intervention) outcomes for all aged persons with congenital heart disease is deplorably lacking and immediately required. The task appears enormous for the >2 million affected patients with congenital heart disease in the United States, but leaving it undone would create even more enormous gaps in knowledge, science, and care. The call to action is here and now; IMPACT has begun the task. Failure to complete it is unacceptable.

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